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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,322	11/06/2001	Derry Roopenian	JL-2010	5668
28120	7590	01/14/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			QIAN, JANICE LI	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

09/993,322

Applicant(s)

ROOPENIAN, DERRY

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/28/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 1-29, 31-46 and 65-80 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57, 60, 61, 64, 85, 86 is/are allowed.
- 6) ☒ Claim(s) 47-56, 58, 59, 62, 63 and 81-84 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment, Declaration of Roopenian, and response filed 10/28/03 have been entered. Claims 30, 47, 49, 52, 54, 60, 61, 64 have been amended. Claims 81-86 are newly added. Claims 30, 47-64, and 81-86 are under current examination.

#### ***Oath/Declaration***

The objection is withdrawn since the provisional applications have been identified in the application data sheet.

#### ***Specification***

The purposed revised abstract could not be found in papers submitted 10/28/03. Another copy of the revised abstract is requested.

#### ***Claim Rejections***

Claim 30 is objected to because an article should precede the word, "inhibitor" in line 9, and the phrase "candidate inhibitor" in line 13.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 47-56, 58, 59, 62, 63, 81-84 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 47-56, 81-84 are drawn to a method for identifying a candidate agent for FcRn-mediated *drug delivery*, which requires delivering a drug to a target cell, yet, the candidate agent is a FcRn binding partner, and the criteria for identifying such agent as stated in step c is whether it could substantially increase the amount of the agent in the blood stream, as such, the method only identifies whether an agent (formulation) would bind to FcRn or staying in the blood stream, it does not identify a candidate agent that promote FcRn-mediated drug delivery since the drug stays in the blood stream while binding to the FcRn rather than delivered to a target cell.

Claims 48, 53, 58, 59, 62, 63, 81, 82 state that the candidate agent or FcRn binding partner is *any* immunoglobulin or any portion thereof, yet, the specification teaches that only IgG Fc region binds FcRn, thus, in light of the specification and the knowledge of the skilled, the claims do not appear to be enabled.

The previous rejection under this section with respect to the unpredictability of the knockout/transgenic mice is withdrawn in view of the response and Declaration.

### ***Conclusion***

Claims 57, 60, 61, 64, 85, 86 are allowable.

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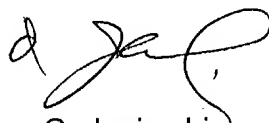
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942 (571-272-0730, after the Office relocation in January 14, 2004). The examiner can normally be reached on 9:30 am - 6 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JANICE LI  
PATENT EXAMINER



Q. Janice Li  
Patent Examiner  
Art Unit 1632



January 9, 2004